



The effect of foot reflexology on constipation: A systematic review and meta-analysis

Azari, Z. A., Mirghafourvand, M., Hughes, C., & Havizari, S. (2020). The effect of foot reflexology on constipation: A systematic review and meta-analysis. *Shiraz E-Med Journal*, 22(1), 1-11. [e100585]. <https://doi.org/10.5812/semj.100585>

[Link to publication record in Ulster University Research Portal](#)

Published in:
Shiraz E-Med Journal

Publication Status:
Published online: 12/10/2020

DOI:
[10.5812/semj.100585](https://doi.org/10.5812/semj.100585)

Document Version
Author Accepted version

General rights
Copyright for the publications made accessible via Ulster University's Research Portal is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy
The Research Portal is Ulster University's institutional repository that provides access to Ulster's research outputs. Every effort has been made to ensure that content in the Research Portal does not infringe any person's rights, or applicable UK laws. If you discover content in the Research Portal that you believe breaches copyright or violates any law, please contact pure-support@ulster.ac.uk.

The effect of foot reflexology on constipation: A Systematic Review

Zahra Anjoman Azari¹, Ciara Hughes², Mojgan Mirghafourvand^{3*}, Shiva Havizari⁴

¹MSc Student in Midwifery, Student Research Committee, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

² Science Committee- Senior Lecturer, School of Health Sciences, University of Ulster- r- Supervisor Adviser in drafting a proposal - Preparing the final report and compiling the article- 25 hours

³Associate Professor, Social Determinants of Health Research Center, Department of Midwifery, Tabriz University of Medical Sciences, Iran.

⁴ MSc Student in Counseling in Midwifery, Student Research Committee, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

***Corresponding author:** Mojgan Mirghafourvand, Social determinants of Health Research Center, Tabriz University of Medical Sciences, Tabriz, Iran. Email: mirghafourvand@gmail.com

Abstract

Objectives: Reflexology is an ancient healing method and a popular type of Complementary and Alternative Medicine (CAM) used for improving constipation symptoms.

Design: Systematic review and meta-analysis.

Materials and Methods

Search methods

All parallel clinical trials evaluating the effect of foot reflexology on constipation symptoms (as the primary outcomes) will be reviewed in a wide range of medical conditions. The PICO framework was used as a tool to search for articles. Nine electronic databases were systematically searched to detect any relevant Randomized Clinical Trials (RCTs).

Selection criteria

The methodological quality of the articles was independently assessed by two authors using the Cochrane Risk of Bias tool. Overall, seven studies related to a wide range of conditions were found to meet all the inclusion criteria.

Data collection and analysis

Data were extracted from the studies that met the selection criteria based on the study population, pre-defined intervention methodology and outcomes. The primary outcomes included the improvement of constipation symptoms and the frequency of bowel movements. The Standardized Mean Difference (SMD) was then measured and the 95% CI was obtained for the mean score of constipation. Random effects were reported instead of fixed effects due to the high heterogeneity.

Results

Assessment quality of articles

Out of the 688 articles retrieved from the databases, 667 titles, nine abstracts and 12 full texts were reviewed, and seven of the articles were ultimately included in this study, out of which six entered the meta-analysis. Two reviewers carefully assessed the included articles independently, and the studies not meeting the inclusion criteria were wholly excluded. The methodological quality of most of the trials was poor. One of the trials reported no significant differences in the severity of constipation after reflexology treatment (Tovey, 2002) and one study failed to show a significant improvement in terms of constipation frequency, stool frequency and stool consistency in the reflexology group compared to the control group (Canbulat Sahiner et al., 2017). One high-quality RCT (Jeanette Susan Gordon, 2007) and three other trials demonstrated the superiority of reflexology to other treatments for the improvement of constipation symptoms. The results of the meta-analysis showed that foot reflexology has a significant effect on the constipation score (SMD:-0.76; 95% CI: -1.34 to -0.18; $P<0.0001$; $I^2=84\%$).

Conclusions

Foot reflexology can effectively improve constipation symptoms; however, clinical trials with better designs are recommended due to the high diversity in the study methods.

KeyWords: Foot reflexology, foot massage, constipation

INTRODUCTION

Reflexology is an ancient healing method (1), and a popular type of Complementary and Alternative Medicine (CAM) that can be easily applied even by the patient and has little chance of side-effects (2). In this method, the feet (often the foot sole) represent the entire body and applying controlled pressure on particular reflex zones on the feet can stimulate their interconnected internal organs (3). The purpose of this treatment is to create balance in the function of the body systems (4); by its medical definition, the purpose is to facilitate homeostasis (5). Constipation is a common gastrointestinal disorder in both adults and children (6). The prevalence of constipation is reported to be as high as 30% in the general population (7).

Constipation is associated with a lower quality of life (8) and some undesirable symptoms (9) and is generally divided into a primary (idiopathic) and a secondary type. Primary constipation is also categorized as: (1) Normal transit, (2) Slow transit, which indicates a prolonged transit time in the colon, and (3) Dyssynergic constipation, referring to an abnormal rectal discharge or functional impairment with no anatomical or physiological etiology (10). Secondary constipation may be associated with endocrine, metabolic or neurologic diseases or may be due to the continuous use of laxatives and other drugs (10-12).

The first-line treatment of constipation involves increasing dietary fiber and fluid consumption and proper laxative use (13, 14). Nevertheless, laxatives are expensive and have some side-effects (15). As a CAM, reflexology has been used to improve constipation symptoms (4). Previous systematic reviews on the subject have merely used abdominal massage or hand reflexology. Some high-quality CTs have measured the effect of foot reflexology on constipation symptoms. The present systematic review was conducted to

critically evaluate the data from RCTs of foot reflexology as a treatment for constipation due to any medical condition.

Materials and Methods

Study selection

Randomized, controlled, clinical trials evaluating the effect of foot reflexology on constipation symptoms were included in this systematic review. The English databases systematically searched included PubMed, Cochrane Library, Web of Science, Embase, Google Scholar and Scopus and the Iranian databases included Scientific Information Database and Magiran, which were all searched for articles published from November 2017 to February 2018 without time limitations. The PICO framework was used as the article search tool. The 'Population' consisted of pediatric, adult or older patients with a diagnosis of constipation receiving foot reflexology. The population was compared with 'Controls' receiving other treatments. The 'Intervention' consisted of foot reflexology. The primary 'Outcome' in this study consisted of constipation symptoms, which were measured using the Modified Constipation Assessment Scale (MCAS), the Constipation Assessment Scale (CAS), which is a two-part questionnaire inquiring about children's defecation characteristics, the Clayden Constipation Questionnaire (CCQ) and the Bristol Stool Scale. The MESH terminology used in the search included "foot reflexology" OR "foot massage" combined with "constipation". According to this search, there were no systematic reviews of clinical trials on the effect of foot reflexology on constipation in whatever conditions. Overall, seven studies met all the inclusion criteria.

Two independent reviewers selected the studies according to the pre-defined inclusion and exclusion criteria. The exclusion criteria for the study consisted of: (1) The absence of a

control group; (2) Receiving any other type of reflexology or massage treatment other than foot reflexology.

Data extraction

A pre-specified form was used for the data extraction that gathered the author's name, year of publication, type of clinical trial, country, participant characteristics, age range, number of participants in the foot reflexology and control groups, measurement tools, follow-up time, treatment regimen and results.

Assessment of risk of bias

The methodological quality of the articles was assessed independently by two reviewers using the Cochrane Risk of Bias tool (16) and disagreements regarding the extracted data were resolved by a third researcher. The methodological information extracted for the assessment of internal validity included sequence generation, allocation concealment, blinding of the participants or personnel, number and reasons for participant's loss to follow up and use of validated outcome measures (17).

Data synthesis and analysis

The pooled standardized mean difference (SMD) and 95% confidence interval (CI) were calculated for the mean score of constipation. Heterogeneity was assessed using the Cochrane Q-test and the Higgins I^2 index (18). Random effect was reported instead of fixed effect due to the high heterogeneity.

Whenever more than ten studies are entered into a meta-analysis, the possibility of publication bias should also be investigated (19). The present study did not need to report any publication

bias due to the small number of analyzed studies. The meta-analysis was conducted using RevMan 5.0 (Cochrane Collaboration, Copenhagen, Denmark).

Results

The search led to the retrieval of 688 articles. After reviewing the article titles or abstracts, the full text of 12 potentially eligible studies was evaluated and five articles were excluded for the following reasons: (1) Absence of a control group; (2) Being descriptive; (3) The participants receiving another type of reflexology (abdominal massage or other type of massage). Finally, seven articles were entered into this study, and a total of 539 participants were consequently analyzed and each study's sample size varied. The trials were carried out in different countries and their treatment period ranged from six days to twelve weeks (Fig. 1).

Risk of bias results

In assessing the methodological quality of the included studies, more than 50% had a low risk of bias for random sequence generation and selective outcome reporting. Three studies reported the method of generating allocation sequences (using a table of random numbers and a computer), but there were no notes of random allocation concealment in them (20-22). Only one study reported random allocation concealment (23). Also, only one of the seven trials reported both the generation of allocation sequences (using the table of random numbers and a computer) and allocation concealment (using similar opaque envelopes); (24). In regarding blinding of participant and personnel, two studies and in terms of blinding of outcome assessor and incomplete outcome data, three studies (less than 50% of all studies) had low risk of bias. In two studies participants were blinded to allocation of groups by nonspecific massage (21, 25). In three studies, it was unclear whether or not the participants were blinded (20, 22, 26). One trial reported that the participants were not blinded (24), and at last, one study reported

assessor blinding to the group allocations within a single-blind design (23); (Table 1, Figure

2). *Characteristics of included studies*

While two of the studies were conducted on women only (21, 26), the five others included adults and children of both genders. The age of the participants differed from 1 to 65 years. The sample size of the studies varied from 34 (25) to 184 (24). The follow-up periods ranged from four to 12 weeks, and the countries of the selected studies included Iran, Turkey and the UK. The outcome measures consisted of subjective outcomes, including constipation score and stool consistency, and the objective outcome included bowel frequency. The treatments were slightly different from each other, and the overall frequency of treatment ranged from six to 84 sessions. In two of the studies, instruments such as oil or cream were used for foot massage (20, 22). **Instructions were given for foot massage in one of the studies** (24). In two studies, the control group was administered the same procedure as the intervention group except that it did not receive foot reflexology (21, 25). The data collection tool used in the study by Elbasan et al. was the Modified Constipation Assessment Scale (MCAS) and the level of constipation improvement was reported as mean and standard deviation (20). Ghaffari et al. (26), Gillespie et al. (23) and Fakhzade et al. (21), also described the constipation score using the Constipation Assessment Scale (CAS) as mean and standard deviation. Canbulat Sahiner et al. used a two-part questionnaire developed by the researchers and reported the stool number and stool consistency as categorical variables in number and percentage (22). Gordon applied the Clayden Constipation Questionnaire for assessing constipation characteristics and the Bristol Stool Scale for evaluating bowel movements and reported the results as mean and standard deviation (24). In all the studies, the intervention group received foot reflexology treatment. Meanwhile, in one trial, the intervention and control groups both received a neurodevelopmental treatment program (20). In one trial, the control group received no treatments (26). In one study, there were three study groups, and one received foot reflexology,

the other received abdominal massage and the third one received no interventions except the routine care (23). In one trial, nonspecific massage was given to the control group (21). In another trial, both the intervention and control groups received toilet/diet/motivation training (22), and in another trial, three groups were assessed: Group 1 (routine care), Group 2 (foot massage along with the routine care) and Group 3 (foot reflexology along with the routine care); (24).

The results of the study by Elbasan et al. demonstrated that although reflexology was effective in improving the symptoms of constipation, the difference between the group receiving reflexology combined with neurodevelopmental therapy and the group receiving neurodevelopmental therapy alone was not statistically significant (20). The results of the study by Ghaffari et al. showed significant differences in the mean constipation scores after reflexology (26). Gillespie et al. found that constipation severity reduced significantly with foot reflexology compared to abdominal massage and routine care from days three to six after the treatment. Foot reflexology improved the symptoms of constipation better than abdominal massage from days three to six after the treatment, but the difference was not statistically significant. There were significant differences between foot reflexology and abdominal massage in comparison with routine care in terms of constipation symptoms from days three to six after the intervention (23). According to the results of a study by Fakhrzade et al., the difference was significant in the severity of constipation between the foot reflexology and nonspecific massage groups (21). The results of Tovey's trial did not show significant differences in constipation improvement between the foot reflexology and control groups (25).

The Results of the study by Canbulat Sahiner et al. showed no significant differences in terms of defecation frequency and defecation consistency between the foot reflexology and control groups (22). Gordon et al. conducted a study with three groups, including the control group, the massage group and the reflexology group, and showed that bowel frequency and

constipation score and sub-scores (soiling, pain, medicine use, general health and behavior), differed significantly between the groups. In that study, bowel frequency differed from baseline in all the groups, but the greatest improvement was observed in the reflexology group. There was also a significant difference between the reflexology and control groups but no significant differences between the massage and control groups. There was also a significant difference between the reflexology and massage groups in terms of the total constipation score, although the bowel frequency scores did not differ significantly between them (24) (Table 2).

Result of meta-analysis

The pooled SMD using the random effect model for the foot reflexology group compared to the control group was -0.76 (95% Confidence Interval: -1.34 to -0.18; $P=0.010$). A significant heterogeneity was observed ($I^2=84\%$, $P<0.0001$). Publication bias was not assessed.

Discussion

The analysis of the data from seven studies showed that foot reflexology is associated with significant improvements in subjective outcomes, including constipation scores and stool consistency; however, foot reflexology did not result in a significant improvement in bowel frequency as an objective outcome. The quality of most included studies was not high.

The results of this review study can be compared with the results of previous studies, even though there were no systematic reviews of studies conducted on the effect of foot reflexology on constipation symptoms compared to other treatments. Cherniack conducted a systematic review entitled "The use of complementary and alternative medicine to treat constipation in the elderly" and included a study by S. Woodward on 19 participants receiving 35-45-min sessions of foot reflexology every week, in which ten of the participants showed improvements in colon transit time after the intervention (11). Wang et al. and Hussain et al. performed systematic reviews that included a single-blind trial on reflexology conducted by

Tovey that evaluated the effectiveness of reflexology on the irritable bowel syndrome. These systematic reviews demonstrated that no statistically significant changes were observed either within or between the reflexology and sham foot massage groups in that study (27, 28).

The primary treatment options (10), for constipation often include non-medical treatments (8). Although certain types of laxatives have some benefits for constipation symptoms, they have some side-effects when used in the long term (29-31). Reflexology is a popular type of CAM and an ancient healing method, (32) that is commonly used in clinical practice and has become increasingly prevalent in various health care areas (33). Song et al. (2015) performed a systematic review on self-administered foot reflexology in patients with chronic health conditions and included three Randomized Controlled Trials (RCTs) and one before-after study. The results of the studies included on self-administered foot reflexology in patients with chronic conditions such as type-2 diabetes, hypertension or urinary incontinence showed insufficient evidence to determine the treatment effectiveness (34). Nonetheless, most of the cases claimed that reflexology was free of side-effects (3). Zeng et al. carried out a systematic review entitled "Complementary and Alternative Medicine in Hospice and Palliative Care" and included 17 studies, with two of them evaluating the efficacy of reflexology in improving the QoL. In one of the studies, 12 patients were randomly divided into two groups to receive reflexology or placebo treatment. The study evaluated constipation and several other symptoms in both groups, and a short-term improvement was reported in terms of QoL and constipation in them (35).

Strengths and limitations

The strengths of the present study include being among the first systematic reviews and meta-analyses of foot reflexology for improving constipation symptoms. Previous systematic studies have reviewed the effects of abdominal massage on constipation. In addition, the present study considered objective outcomes in addition to subjective outcomes for this review.

According to the existing literature, foot reflexology is an appropriate integrative treatment for symptom alleviation in patients with constipation; however, further research is needed for the review of the style of reflexology applied using well-designed and high-quality RCTs (36),

The limitations of this systematic review include the trials using different types of controls depending on what they consider 'foot reflexology' or the control groups of the studies receiving another type of CAM (such as abdominal massage or nonspecific foot massage). In addition, the nature of this intervention is such that blinding the participants and performers is difficult. Sham reflexology is one example of the methods used to blind the participants on foot reflexology; however, these methods yield mixed results due to their uncertain reliability as a placebo. Most of the measurement tools used in the studies were subjective. A few studies used objective measurement tools, such as bowel movement or stool frequency forms. Also, even though the major English and Persian databases were searched comprehensively, studies published in other languages are missing on the subject.

Conclusion and future research

This study reviewed the effectiveness of foot reflexology in relieving constipation symptoms. Although the majority of the assessed articles in this review showed the effectiveness of foot reflexology for constipation symptom relief, due to the poor quality of the articles, there is no sufficient evidence to judge the effectiveness of foot reflexology on the improvement of constipation symptoms. Better-designed randomized, controlled, clinical trials are therefore recommended to compare the effect of foot reflexology on constipation symptoms with other treatments, such as massage or standard treatments. Randomization, allocation concealment and proper blindness of the participants, performers and outcome assessors are essential for higher-quality trials. Valid tools to measure the outcomes should also be considered. Finally,

it is necessary for all authors to include international standard statements such as the CONSORT statement in reports of their trial results.

Declarations

Conflict of interests

The authors declare that they have no conflicts of interest with regard to the research, authorship and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this paper.

Ethical approval

No need for ethical approval

Guarantor

No guarantor

Contributor ship

ZAA, SH, CH and MM (corresponding author) participated in the study designing. ZAA and SH searched the literature and selected studies, extracted data, assessed quality, and drafted the manuscript. CH and MM (corresponding author) revised the draft and all authors read and approved the final version of the manuscript.

Acknowledgements

No acknowledgements

References

1. Ernst E, Posadzki P, Lee MS. Reflexology: an update of a systematic review of randomised clinical trials. *Maturitas*. 2011;68(2):116-20. Epub 2010/11/30. doi: 10.1016/j.maturitas.2010.10.011. PubMed PMID: 21111551.
2. Zhai J, Mu W, Si J, Li Y, Zhao C, Shang H, et al. Acupuncture for constipation in patients with stroke: protocol of a systematic review and meta-analysis. *BMJ Open* [Internet]. 2018 2018/03//; 8(3):[e020400 p.]. Available from: <http://europepmc.org/abstract/MED/29602854>
<http://europepmc.org/articles/PMC5884333?pdf=render>
<http://europepmc.org/articles/PMC5884333>
<https://doi.org/10.1136/bmjopen-2017-020400>.
3. Ernst E. Is reflexology an effective intervention? A systematic review of randomised controlled trials. *The Medical journal of Australia*. 2009;191(5):263-6. Epub 2009/09/11. PubMed PMID: 19740047.
4. Hughes CM, Krirsnakriengkrai S, Kumar S, McDonough SM. The effect of reflexology on the autonomic nervous system in healthy adults: a feasibility study. *Alternative therapies in health and medicine*. 2011;17(3):32-7. Epub 2011/12/15. PubMed PMID: 22164810.
5. Bishop E, McKinnon E, Weir E, Brown DW. Reflexology in the management of encopresis and chronic constipation. *Paediatric nursing* [Internet]. 2003; 15(3):[20-1 pp.]. Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011448.pub2/abstract>.
6. van den Berg MM, Benninga MA, Di Lorenzo C. Epidemiology of childhood constipation: a systematic review. *The American journal of gastroenterology*. 2006;101(10):2401-9. Epub 2006/10/13. doi: 10.1111/j.1572-0241.2006.00771.x. PubMed PMID: 17032205.
7. Cullen G, O'Donoghue D. Constipation and pregnancy. *Best practice & research Clinical gastroenterology*. 2007;21(5):807-18. Epub 2007/09/25. doi: 10.1016/j.bpg.2007.05.005. PubMed PMID: 17889809.
8. Rungsiprakarn P, Laopaiboon M, Sangkomkarnhang Ussanee S, Lumbiganon P, Pratt Jeremy J. Interventions for treating constipation in pregnancy. *Cochrane Database of Systematic Reviews* [Internet]. 2015; (9). Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011448.pub2/abstract>.
9. Bradley CS, Kennedy CM, Turcea AM, Rao SSC, Nygaard IE. Constipation in Pregnancy: Prevalence, Symptoms, and Risk Factors. *Obstetrics & Gynecology*. 2007;110(6):1351-7. doi: 10.1097/01.AOG.0000295723.94624.b1. PubMed PMID: 00006250-200712000-00022.
10. Lee-Robichaud H, Thomas K, Morgan J, Nelson Richard L. Lactulose versus Polyethylene Glycol for Chronic Constipation. *Cochrane Database of Systematic Reviews* [Internet]. 2010; (7). Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007570.pub2/abstract>.
11. Cherniack EP. Use of complementary and alternative medicine to treat constipation in the elderly. *Geriatrics and Gerontology International*. 2013;13(3):533-8. doi: 10.1111/ggi.12023.
12. Nanji Kashmira S, Ahmed B, Awan S, Qidwai W, Hamid S. Fiber and bulking agents for the treatment of chronic constipation. *Cochrane Database of Systematic Reviews* [Internet]. 2012; (2). Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009656/abstract>.
13. Anderson AS. Dietary factors in the aetiology and treatment of constipation during pregnancy. *British journal of obstetrics and gynaecology*. 1986;93(3):245-9. Epub 1986/03/01. PubMed PMID: 3008805.
14. Derbyshire EJ, Davies J, Detmar P. Changes in bowel function: pregnancy and the puerperium. *Dig Dis Sci*. 2007;52(2):324-8. Epub 2007/01/11. doi: 10.1007/s10620-006-9538-x. PubMed PMID: 17211700.
15. Tytgat G, Heading R, Müller-Lissner S, Kamm M, Schölmerich J, Berstad A, et al. Contemporary understanding and management of reflux and constipation in the general population and pregnancy: a consensus meeting. *Alimentary pharmacology & therapeutics*. 2003;18(3):291-301.

16. Higgins JP, Green S. Cochrane handbook for systematic reviews of interventions 5.1. 0. The Cochrane Collaboration. 2011:33-49.
17. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:d5928. doi: 10.1136/bmj.d5928.
18. Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ (Clinical research ed)*. 2003;327(7414):557-60. doi: 10.1136/bmj.327.7414.557. PubMed PMID: 12958120.
19. Song F, Hooper L, Loke Y. Publication bias: what is it? How do we measure it? How do we avoid it? *Open Access Journal of Clinical Trials*. 2013;2013(5):71-81.
20. Elbasan B, Bezgin S. The effects of reflexology on constipation and motor functions in children with cerebral palsy. *Pediatrics & Neonatology*. 2017.
21. Fakhrzade H, Naeeni M. EFFECT OF FOOT REFLEXOLOGY ON THE SEVERITY OF CONSTIPATION OF ELDERLY WOMEN RESIDING IN KAHRIZAK GERIATRIC NURSING HOME. *The Journal of Urmia Nursing and Midwifery Faculty*. 2016;13(10):825-34.
22. Canbulat Sahiner N, Demirgoz Bal M. A randomized controlled trial examining the effects of reflexology on children with functional constipation. *Gastroenterology Nursing*. 2017;40(5):393-400.
23. Gillespie M, Aydinferd S. Comparison of Effectiveness of Reflexology and Abdominal Massage on Constipation among Orthopedic Patients: A single-blind Randomized Controlled Trial. *Health Sciences*. 2016;5(10):33-40.
24. Gordon JS. The Effectiveness of Reflexology as a Adjunct to Standard Treatment in Childhood Idiopathic Constipation A Single Blind Randomised Controlled Trial: Edinburgh Napier University; 2007.
25. Tovey P. A single-blind trial of reflexology for irritable bowel syndrome. *Br J Gen Pract*. 2002;52(474):19-23.
26. Ghaffari F, Poor Ghaznain T, Shamsalinia A. Effect of Sole Reflex on Pregnant Women's Constipation Severity. *The Iranian Journal of Obstetrics, Gynecology and Infertility*. 2007;10(2):27-38. doi: 10.22038/ijogi.2007.5945.
27. Hussain Z, Quigley E. Systematic review: complementary and alternative medicine in the irritable bowel syndrome. *Alimentary pharmacology & therapeutics*. 2006;23(4):465-71.
28. Wang MY, Tsai PS, Lee PH, Chang WY, Yang CM. The efficacy of reflexology: systematic review. *Journal of advanced nursing*. 2008;62(5):512-20. Epub 2008/05/21. doi: 10.1111/j.1365-2648.2008.04606.x. PubMed PMID: 18489444.
29. Klaschik E, Nauck F, Ostgathe C. Constipation--modern laxative therapy. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2003;11(11):679-85. Epub 2003/09/25. doi: 10.1007/s00520-003-0525-x. PubMed PMID: 14505158.
30. Wald A. Is chronic use of stimulant laxatives harmful to the colon? *J Clin Gastroenterol*. 2003;36(5):386-9. Epub 2003/04/19. PubMed PMID: 12702977.
31. Stickel F, Schuppan D. Herbal medicine in the treatment of liver diseases. *Digestive and liver disease : official journal of the Italian Society of Gastroenterology and the Italian Association for the Study of the Liver*. 2007;39(4):293-304. Epub 2007/03/03. doi: 10.1016/j.dld.2006.11.004. PubMed PMID: 17331820.
32. Hung A, Kang N, Bollom A, Wolf JL, Lembo A. Complementary and Alternative Medicine Use Is Prevalent Among Patients with Gastrointestinal Diseases. *Digestive Diseases and Sciences*. 2015;60(7):1883-8. doi: 10.1007/s10620-014-3498-3.
33. Charlton J, Mackereth P, Tiran D, Donald G. Take me to a clinical reflexologist: An exploratory survey. *Complementary therapies in clinical practice*. 2011;17(2):102-6. doi: 10.1016/j.ctcp.2010.08.002.
34. Song HJ, Choi SM, Seo HJ, Lee H, Son H, Lee S. Self-administered foot reflexology for the management of chronic health conditions: a systematic review. *Journal of alternative and complementary medicine (New York, NY)*. 2015;21(2):69-76. Epub 2015/01/31. doi: 10.1089/acm.2014.0166. PubMed PMID: 25636044.

35. Zeng YS, Wang C, Ward KE, Hume AL. Complementary and Alternative Medicine in Hospice and Palliative Care: A Systematic Review. *Journal of pain and symptom management*. 2018;56(5):781-94.e4. Epub 2018/08/05. doi: 10.1016/j.jpainsymman.2018.07.016. PubMed PMID: 30076965.
36. McCullough J, Liddle S, Sinclair M, Close C, Hughes C. The physiological and biochemical outcomes associated with a reflexology treatment: a systematic review. *Evidence-Based Complementary and Alternative Medicine*. 2014;2014.

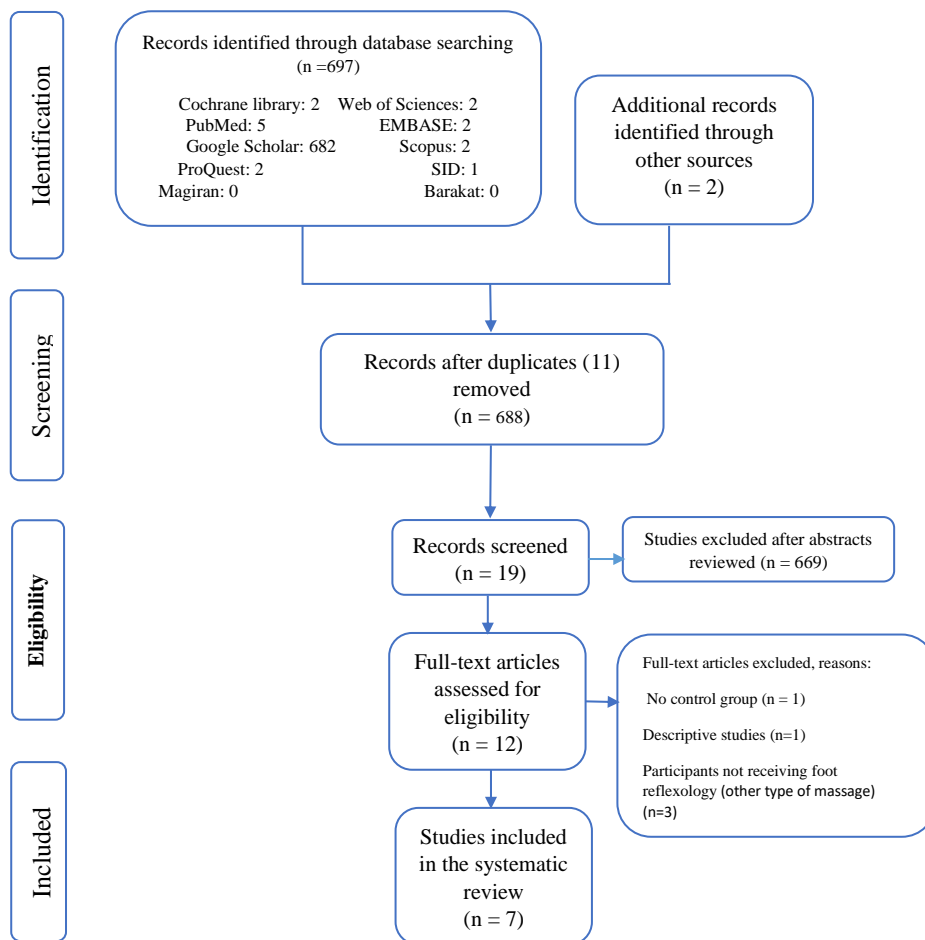
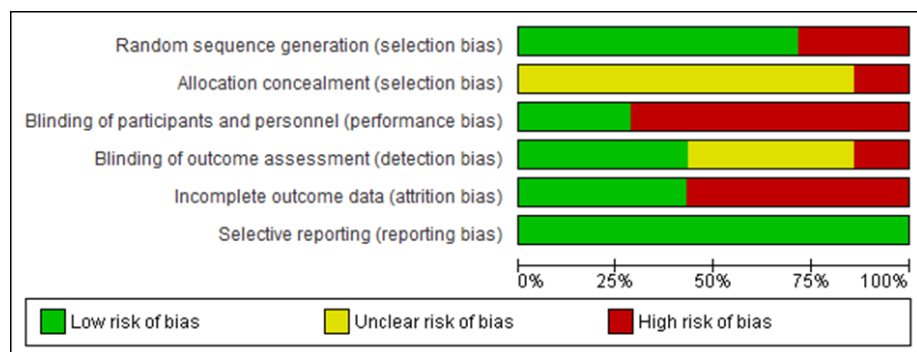


Figure 1. Figure 1 Study flow diagram



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Canbulat Sahiner 2017	+	?	-	?	-	+
Elbasan 2017	+	?	-	?	-	+
Fakhrzadeh 2016	+	?	+	+	+	+
Ghaffari 2007	-	?	-	?	-	+
Gillespie 2016	+	?	-	+	+	+
Gordon 2007	+	?	-	+	-	+
Tovery 2002	-	-	+	-	+	+

Figure 2 Risk of bias graph and summary of all included studies

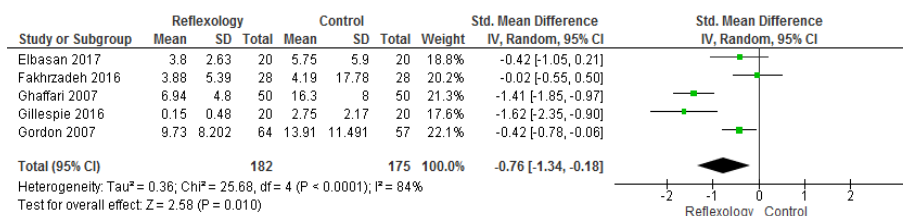


Figure 3. Forest plots of randomized controlled studies. The primary outcomes were improvement of constipation symptoms and frequency of bowel movements.

Table 2. Risk of bias in the included studies		
Bulent Elbasan (2017)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Unclear risk	Simple random sampling was used to assign the participants into two groups
Allocation concealment	Unclear risk	No specific information was given regarding allocation concealment and blinding
Blinding the participants and personnel	High risk	Open-label design
Blinding the outcome assessors	Unclear risk	No information provided
Incomplete outcome data	High risk	Out of 52 children, five in the control group (group 1) and seven in the reflexology group (group 2) dropped out (no note of the reason)
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Ghaffari et al. (2007)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Low risk	Fitted pairs sampling method was used
Allocation concealment	Unclear risk	No specific information
Blinding the participants and personnel	High risk	No blinding of the personnel and participants
Blinding the outcome assessors	Unclear risk	No specific information
Incomplete outcome data	High risk	There were ten losses to follow-up in the control group and 15 in the reflexology group (no note of the reason)
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Gillespie et al. (2016)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Low risk	Random sequence generation was used ("the subjects were allocated to two intervention groups using a table of random numbers")
Allocation concealment	Unclear risk	No specific information
Blinding the participants and personnel	High risk	Open-label design
Blinding the outcome assessors	low risk	The assessor was blinded to the group allocation
Incomplete outcome data	Low risk	There was no loss to follow-up in the control or reflexology groups
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Fakhrzade et al. (2015)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Low risk	The subjects were randomly divided into two groups, their names were coded in the list and then they were randomly included in the study by the codes
Allocation concealment	Unclear risk	No specific information was given regarding allocation concealment
Blinding the participants and personnel	low risk	Non-specific massage was given to the personnel and participants
Blinding the outcome assessors	Low risk	The assessor who measured and recorded the constipation severity was blinded to the group allocation
Incomplete outcome data	Low risk	There was no loss to follow-up
Selective reporting	High risk	Primary outcomes have not been reported.
N. Canbulat Sahiner et al. (2015)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Unclear risk	No specific information
Allocation concealment	Unclear risk	No specific information

Blinding the participants and personnel	High risk	No blinding of the personnel and participants
Blinding the outcome assessors	Unclear risk	No specific information
Incomplete outcome data	High risk	Out of 40 children, there were three losses to follow-up in the intervention group (The reasons included family relocation and unwillingness to continue the study).
Selective reporting	Unclear risk	No specific information
Jeanette Susan Gordon (2007)		
Bias	Authors' Judgment	Support for Judgment
Random sequence generation	Low risk	Random sequence generation (computer-generated permuted block design was used for the random sequence generation)
Allocation concealment	Low risk	Allocation concealment was used (random numbers were placed in sealed opaque envelopes by an independent statistician)
Blinding the participants and personnel	High risk	No blinding of the personnel and participants
Blinding the outcome assessors	Low risk	The assessor who measured and recorded the constipation severity was blinded to the group allocation
Incomplete outcome data	Low risk	Out of 184 participants in the trial, two in the foot reflexology group, four in the foot massage group and two in the control group were lost to follow-up (the reasons were noted)
Selective reporting	Low risk	Primary outcomes have been reported (The primary outcome was the mean number of complete bowel movements over a four-week period, 12 weeks after randomization, identified by the score of the Clayden Constipation Questionnaire (Clayden et al., 2005) for the variable "Bowel Frequency" (Bofreq). The total constipation score was also used as a variable (Conscor). The mean scores of these variables were compared at baseline and 12 weeks later)
P. Tovey (2002) (25)		
Bias	Authors' judgment	Support for Judgment
Random sequence generation	High risk	Random sequence generation was not performed (Randomization by alternation was used. The participants were recruited practice by practice due to the small numbers involved in each practice. Full randomization in these small blocks would have been impractical).
Allocation concealment	High risk	Allocation concealment and blinding was not used
Blinding the participants and personnel	Low risk	Non-specific massage was given to the participants
Blinding the outcome assessors	High risk	No information provided
Incomplete outcome data	Low risk	There were four losses to follow-up in the reflexology group and two in the control groups (no reasons noted)
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Table 2. Risk of bias in included studies		
Elbasan, Bulent, (2017)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Unclear risk	Simple random sampling was used to assign the participants into two groups
Allocation concealment	Unclear risk	No specific information was given regarding allocation concealment and blinding
Blinding of participants and personnel	High risk	Open-label design
Blinding of outcome assessors	Unclear risk	No information provided

Incomplete outcome data	High risk	Out of 52 children, five in the control group (group 1) and seven in the reflexology group (group 2) dropped out (no note of the reason)
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Ghaffari, et al. (2007)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Low risk	Fitted pairs sampling method was used
Allocation concealment	Unclear risk	No specific information
Blinding of participants and personnel	High risk	No blinding of the personnel and participants
Blinding of outcome assessors	Unclear risk	No specific information
Incomplete outcome data	High risk	There was 10 loss to follow up in control group and 15 loss to follow up in reflexology group (no mention about reason)
Selective reporting	High risk	"Primary and secondary outcomes" have not been reported
Gillespie et al. (2016)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Low risk	Random sequence generation was given ("Predicting an attrition rate of 10% the total sample was determined as 60 participants. 20 in each group were therefore included and subjects were allocated by using a randomized numbers table for 2 intervention groups")
Allocation concealment	Unclear risk	No specific information
Blinding of participants and personnel	High risk	Open-label design
Blinding of outcome assessors	low risk	An assessor blinded to the group allocation
Incomplete outcome data	Low risk	There was no loss to follow up in control and in reflexology group
Selective reporting	High risk	Primary and secondary outcomes have not been reported
Fakhrzade et al. (2015)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Low risk	"The subjects were randomly divided into two groups, their names were coded in the list and then, randomly, from the codes, the subjects were included in the study"
Allocation concealment	Unclear risk	No specific information regarding allocation concealment was provided.
Blinding of participants and personnel	low risk	Nonspecific message was given to personnel and participants
Blinding of outcome assessors	Low risk	An assessor blinded to the group allocation measured and recorded constipation severity
Incomplete outcome data	Low risk	There was no lost to follow-up
Selective reporting	High risk	Primary outcomes have not been reported.
Canbulat Sahiner, N. et al. (2015)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Unclear risk	No specific information
Allocation concealment	Unclear risk	No specific information
Blinding of participants and personnel	High risk	No blinding of personnel and participants was given.
Blinding of outcome assessors	Unclear risk	No specific information
Incomplete outcome data	High risk	Out of 40 children, there was 3 lost to follow up in intervention group ("The reasons for departure from the study included family relocation to another city and a desire not to continue with the study").
Selective reporting	Unclear risk	No specific information was given.

Gordon, Jeanette Susan (2007)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	Low risk	Random sequence generation was given ("Computer generated permuted block design random numbers were placed in opaque sealed envelopes by an independent statistician")
Allocation concealment	Low risk	Allocation concealment was given
Blinding of participants and personnel	High risk	No blinding of personnel and participants was given
Blinding of outcome assessors	Low risk	"An assessor blinded to the group allocation measured and recorded constipation severity"
Incomplete outcome data	Low risk	Out of 184 participant in the trial, 2 in foot reflexology, 4 in foot massage and 2 in control group, were lost to follow up (reasons were mentioned)
Selective reporting	Low risk	Primary outcomes have been reported ("The primary outcome was the mean number of complete bowel movements in a 4 week period 12 weeks after randomisation identified by the score on the Clayden Constipation Questionnaire (Clayden et al. 2005) from the variable 'Bowel Frequency' (Bofreq). The total constipation score variable was also used (Conscor). The mean scores for these variables at baseline were compared with the same variables at 12 weeks").
Tovey, P (2002)(25)		
Bias	Authors' judgment	Support for judgment
Random sequence generation	High risk	Random sequence generation was not done ("Randomisation by alternation was used. Participants were recruited practice by practice since, given the small numbers involved in each practice, full randomisation in these small blocks would have been impractical").
Allocation concealment	High risk	Blinding of Allocation concealment was not given
Blinding of participant and personnel	Low risk	Nonspecific massage was given to participants
Blinding of outcome assessment	High risk	No information provided
Incomplete outcome data	Low risk	There was 4 loss to follow up in reflexology and 2 in control groups (no reason mentioned)
Selective reporting	High risk	Primary and secondary outcomes not been reported.

علت ریزش اگر گزارش شده باشد کم خطر
 Commented [w1]: زده شود

Table 1: Characteristics of included studies									
Author (s) Location/(year)/ Study design*	Study population	Age of participants	Treatment group	Type of blinding	Intervention	Comparison	Number of patient in both group	Method of diagnosis	results
Elbasan, Bulent, et al. Turkey / (2017) ⁽²⁰⁾	40 children diagnosed with CP	3-15 years	Group 1: Neurodevelopmental therapy Group 2: Foot reflexology with neurodevelopmental therapy	No blinding	Foot reflexology with neurodevelopmental therapy (twice a week, with each session lasting for 20 minutes for a total duration of eight weeks)	Neurodevelopmental therapy (each session lasting for 45-60 minutes)	40 children using simple random sampling assigned to two groups of 20. Number of drop-outs (Group 1: 5; Group 2: 7) Group 1: 25 Group 2: 27	Modified Constipation Assessment Scale (MCAS)	Foot reflexology in combination with neurodevelopmental therapy can decrease constipation scores significantly (P=-0.081)
Ghaffari, et al. Iran / (2007) ⁽²⁶⁾	100 pregnant women with constipation	No information given	Group 1: Foot reflexology Group 2: Control	No blinding	Foot reflexology (weekly sessions lasting 30 minutes, for six weeks)	No intervention	Foot reflexology (n=50) Control (n=50) (Randomized=125, group 1=65, Group2=60, Drop-outs in group 1 =15, in group 2 =10)	Constipation Assessment Scale (CAS)	Foot reflexology improved constipation symptoms significantly (P<0.001).
Gillespie et al., Iran / (2016) ⁽²³⁾	60 hospitalized patients with scores of 5 and above on the CAS	>18 years	Group 1: Foot reflexology Group 2: Abdominal massage Group 3: No intervention (received routine care)	Single-blind	Foot reflexology with routine care, each session lasted 40 minutes; abdominal massage with routine care, 20 minutes daily for six days	No intervention or abdominal massage	Foot reflexology (n=20) Abdominal massage (n=20) Control (n=20) (Randomized =60, no drop-outs in the groups)	Constipation Assessment Scale (CAS)	There were no statistically significant post-intervention differences between the groups in terms of constipation severity until the second day of the intervention (P>0.05), but from the 3 rd day until the 6 th day after the intervention, a significant difference was observed (P<0.05).
Fakhrzade et al. Iran / (2015) ⁽²¹⁾	28 older women with constipation	>65 years	Group 1: Foot reflexology Group 2: Non-specific massage	Double-blind	Foot reflexology given weekly for six weeks and each session lasting 35-40 minutes	Non-specific massage	Foot reflexology (n=28) Nonspecific massage (n=28) (Randomized=56,	Constipation Assessment Scale (CAS)	Significant differences were observed in the severity of constipation in both groups at the end of the first six weeks (P<0.001).

							no drop-outs in the groups)		
Canbulat Sahiner, et al. Turkey / (2017)⁽²²⁾	37 children with functional constipation	3-6 years	Group 1: Foot reflexology and toilet/diet/ motivation training Group 2: Toilet/diet/ motivation training	No blinding	Each child received 10-min foot massage for five days a week, and toilet/diet/motivation training was given to their parents for 30 min once a week for a period of four weeks	Toilet/diet/ motivation training	Received reflexology and toilet/diet/ motivation training (n=20), toilet/diet/ motivation training (n=20) (Randomized=37, Drop-outs in group 1 =3, in group 2=0)	A two-part questionnaire consisting of 23 questions. A table was included in the second part of the questionnaire, in which the defecation frequency and quality were recorded. The status of the child was recorded in this table at the end of each week.	No significant differences were detected between the intervention and control groups in terms of constipation frequency (P>0.05); stool frequency increased in both groups from the second week onwards. Stool consistency improved as of the second week. There was a difference between the intervention and control groups (P = .032) in the following weeks, but it never reached the level of statistical significance (P>0.05) ".
Gordon, Jeanette Susan UK /(2007)⁽²⁴⁾	184 Children diagnosed with chronic idiopathic (functional)	1-12 years	Group 1: Control- Routine care only Group 2: Foot massage + routine care Group 3: Reflexology + routine care	Single blind (assessor was blinded)	The parents/caregivers were taught simple foot massage and reflexology techniques by the nurse to use daily on the patient	Standard care	Group 1: 59 Group 2: 59 Group 3: 66 (Randomized=184 , Drop-outs in group 1 =2, group 2 =4 Group 3 =2)	The number of complete bowel movements per four-week period was recorded in the forms as a four-week diary. The Bristol Stool Chart was used to help record the bowel movements.	Reflexology improved the total constipation score, bowel movement frequency and general health significantly after 12 weeks of the intervention (P=0.047). Reflexology and massage improved the constipation score significantly, but not the bowel movement frequency (P=0.063).
Tovey, P UK / (2002)⁽²⁵⁾	34 patients with IBS based on the Rome Criteria (28 women and six men)	19-72 years	Group 1: Reflexology Group 2: Non-specific massage	Single-blind	Intervention consisted of six (four weekly and two fortnightly) 30-min sessions. IBS symptoms were completed two weeks before the first session, during the intervention, two weeks after and again two weeks later at the first follow-up and	Control (non-specific massage) group exposed to exactly the same number of sessions as the experimental group	Foot reflexology (n=19) Control (nonspecific massage; n=15) (Randomized=34, drop-outs in group 1 =0, in group 2 =0)	IBS symptoms were assessed daily on a five-point (0 to 4) scale. The forms were completed by all the participants two weeks before the first session, during the intervention, two weeks after the intervention and again two weeks later at the first follow-up and finally three months	There was no evidence of any differences between the groups (P=0.47).

					finally three months after the last session at the second follow-up			after the last session at the second follow-up.	
* Randomized Controlled Trial									

Appendix 1. Electronic search strategy	
Appendix 1. The electronic search strategy	
Database:	PubMed
Date of Last Search:	18 July 2018
Search Strategy:	{("foot" [MeSH Terms] OR "foot" [All Fields]) AND "massage" [MeSH Terms]} AND "constipation" [MeSH Terms]